PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1) D:6-7-06

Date of mailing *(day/month/year)*	07.03.2006
Applicant's or agent's file reference 1023-360WO01	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2005/008881	16.03.2005	16.03.2004

Applicant
MEDTRONIC, INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Koster, A Tel. +49 30 25901-726

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1023-360WO01	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US2005/008881	International filing date *(day/month/year)* 16.03.2005	Priority date *(day/month/year)* 16.03.2004
International Patent Classification (IPC) or national classification and IPC A61B5/0205, A61N1/05, A61N1/365, G06F17/00, G08B21/06		
Applicant MEDTRONIC, INC. et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.01.2006	07.03.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Kronberger, R Telephone No. +49 30 25901-559

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2005/008881

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-19 as originally filed

   Claims, Numbers

   1-26 filed with telefax on 16.01.2006

   Drawings, Sheets

   1/4-4/4 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-26
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-26
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V.

1 Reference is made to the following documents:

D1: US-A-5 732 696 (RAPOPORT ET AL) 31 March 1998 (1998-03-31)

D2: US 2002/193839 A1 (CHO YONG KYUN ET AL) 19 December 2002 (2002-12-19)

D3: US 2003/163059 A1 (POEZEVERA YANN ET AL) 28 August 2003 (2003-08-28)

D4: US 2002/193697 A1 (CHO YONG KYUN ET AL) 19 December 2002 (2002-12-19)

D5: US 2003/153953 A1 (PARK EULJOON ET AL) 14 August 2003 (2003-08-14)

D6: WO 02/100267 A (COMPUMEDICS LIMITED; BURTON, DAVID; ZILBERG, EUGENE) 19 December 2002 (2002-12-19)

2 INDEPENDENT CLAIMS 1, 20

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

Document D5 discloses (the references in parentheses applying to this document): a medical system (see fig.3-4) comprising

- a plurality of sensors (102,103), each of the sensors generating a signal as a function of at least one physiological parameter of a patient; and
- an implantable medical device (fig.3) that includes a processor (460) that monitors a plurality of physiological parameters of the patient based on the signals output by the sensors (see fig.2, steps 202-208), and determines a probability of the patient being asleep (determining whether the patient is asleep corresponds to determining a probability of 0 or 1 of the patient being asleep) based on the physiological parameters (see fig.2, step 210 and par.55).

2.2 From this the subject-matter of claim 1 differs in that

- the processor determines a metric based on the physiological parameters.

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2.2 From this the subject-matter of claim 1 differs in that

- the processor determines a metric based on the physiological parameters.

2.3 It is noted that the medical system known from D5 provides the same advantages as those alleged on par.18 of the application (see D2, par.55: the patient is determined to be in a sleep state if one of the parameters is below a threshold. Therefore also in D5 failure of any one physiological parameter to accurately indicate whether the patient is sleeping may be less likely to prevent the device from accurately indicating whether the patient is sleeping).

2.4 The problem solved by claim 1 can thus be regarded as how to provide an alternative combination of the physiological parameters for sleep detection.

2.5 However the combination of two physiological parameters into one metric is well known in the field of implantable medical devices (see for example D2, par.7-8,11,15 and 64-67 showing a similar implantable device wherein parameters from activity and minute ventilation sensors are used for sleep detection and are blended for providing an adapted pacing rate), especially as D5 teaches towards the use of different methods of combining the parameters (two such methods are described in D5, par.55).
Therefore the solution proposed by claim 1 (see §2.2) is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed (see §2.4).
Hence claim 1 can not ne regarded as inventive (Article 33(3) PCT).

2.6 The same arguments apply to independent claim 20.

2.7 It is noted that the problem of sleep detection is addressed in many implantable devices (e.g. D2, fig.3d; D3, fig.1; D4, fig.6; D5, fig.2). In order to obtain improved accuracy in sleep detection the skilled person would consider it as a normal option to apply probability methods known from polysomnograph systems as shown in D1 (see also D4, par.10-13,26 teaching towards implementing polysomnograph features in an implantable device).

3 DEPENDENT CLAIMS

Dependent claims 2-19, 21-26 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

Re Item VI.

1 Reference is made to the following document:
D7: EP-A-1 437 159 (PACESETTER, INC) 14 July 2004 (2004-07-14)

1.1 D7 has a filing date of 12.01.2004 and claims priority of 10.01.2003.

Re Item VIII.

1 Note: Article 6 PCT
In the embodiment of the invention described on page 17/l.3-12 a sleep metric value is determined based on one physiological parameter.
This embodiment therefore does not fall within the scope of the independent claims 1 and 20, which demand the sleep metric being determined based on a plurality of physiological parameter (see applicants telefax dated 13.01.2006 p.4/2nd.par). This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear (Article 6 PCT).

CLAIMS:

1. A medical system comprising:

a plurality of sensors, each of the sensors generating a signal as a function of at least one physiological parameter of a patient; and

an implantable medical device that includes a processor that monitors a plurality of physiological parameters of the patient based on the signals output by the sensors, and determines a value of a sleep metric that indicates a probability of the patient being asleep based on the physiological parameters.

2. The system of claim 1, wherein the physiological parameters comprise at least one of activity level, posture, heart rate, electrocardiogram morphology, respiration rate, respiratory volume, core temperature, or subcutaneous temperature,.

3. The system of claim 1, wherein physiological parameters comprise at least one of blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity, muscular tone, arterial blood flow, brain electrical activity, eye motion, or galvanic skin response.

4. The system of claim 1, wherein the processor determines a variability of at least one of the physiological parameters, and determines the sleep metric based on the variability.

5. The system of claim 1, wherein the processor determines at least one of a mean value or a median value of at least one of the physiological parameters, and determines the sleep metric based on the at least one of the mean value or the median value.

6. The system of claim 1, wherein the processor determines a value of each of a plurality of sleep metrics, each of the plurality of values determined based on a respective one of the physiological parameters.

7. The system of claim 6, wherein the processor determines a value of an overall sleep metric based the values of the plurality of sleep metrics.

8. The system of claim 7, wherein the processor determines the value of the overall sleep metric by averaging the values of the plurality of sleep metrics.

9. The system of claim 8, wherein the processor applies a weighting factor to at least one of values of the plurality of sleep metrics.

10. The system of claim 1, further comprising a memory to store a threshold value, wherein the processor compares the value of the sleep metric to a threshold value and determines whether the patient is asleep based on the comparison.

11. The system of claim 10, wherein the memory stores a plurality of threshold values, and the processor compares the value of the sleep metric to each of the threshold values and determines a sleep state of the patient based on the comparison.

12. The system of claim 11, wherein the processor determines whether the patient is in one of a rapid eye movement (REM) sleep state and a nonrapid eye movement (NREM) sleep state.

13. The system of claim 10, further comprising a user interface, wherein a user selects the threshold via the user interface.

14. The system of claim 10, wherein the processor controls delivery of a therapy to the patient by the implantable medical device based on the determination of whether the patient is asleep.

15. The system of claim 10, wherein the processor stores information indicating when the patient is asleep within the memory for retrieval by a user.

16. The system of claim 1, wherein the implantable medical device includes the sensor.

17. The system of claim 1, wherein the implantable medical device is coupled to the sensor via a lead.

18. The system of claim 1, wherein the implantable medical device is wirelessly coupled to the sensor.

19. The system of claim 1, wherein the implantable medical device comprises at least one of an implantable neurostimulator or an implantable pump.

20. A system comprising:

means for monitoring a plurality of physiological parameters of a patient; and

an implantable medical device that includes means for determining a value of a sleep metric that indicates a probability of the patient being asleep based on the physiological parameters.

21. The system of claim 20, further comprising means for generating at least one signal as a function of the physiological parameters, wherein the means for monitoring comprises means for monitoring the physiological parameters based on the signal.

22. The system of claim 20, wherein the means for determining a sleep metric comprises means for determining a value for each of a plurality of sleep metrics, each of the plurality of values determined based on a respective one of the physiological parameters.

23. The system of claim 22, wherein the means for determining a value of a sleep metric comprises means for determining a value of an overall sleep metric based the values of the plurality of sleep metrics.

24. The system of claim 22, further comprising means for comparing the value of the sleep metric to a threshold value and determining whether the patient is asleep based on the comparison.

25. The system of claim 24, wherein the implantable medical device further comprises:

means for delivering a therapy to the patient; and

means for controlling delivery of a therapy to the patient by the therapy delivery means based on the determination of whether the patient is asleep.

26. The system of claim 24, further comprising means for storing information indicating when the patient is asleep for retrieval by a user.